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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/056,019 | 04/07/1998 | ELAINE I. TUOMANEN | 44158/207989(5853-2) | 4774 |

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ALSTON AND BIRD LLP
ST. JUDE CHILDREN'S RESEARCH HOSPITAL
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

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| EXAMINER |
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MINNIFIELD, NITA M

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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|----------------------------------------|--|
| Office Action Summary | Application No. 09/056,019 | Applicant(s) TUOMANEN ET AL. | |
| | Examiner N. M. Minnifield | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-63,66-72,74-78,80-83,87-89,92-95,98 and 111-122 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59,62,63,111,114 and 115 is/are allowed.
- 6) ☒ Claim(s) 46-58,60,61,66-72,74-78,80-83,87-89,92-95,98,112,113 and 116-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. <u>2/10/04</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9/5/03</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 5, 2003 has been entered.

2. Applicants' amendment filed September 5, 2003 is acknowledged and has been entered. Claims 1-45, 64, 65, 73, 79, 84-86, 90, 91, 96, 97 and 99-110 have been canceled. Claims 46, 53, 54, 59-63, 67-72, 74, 75, 80, 81, 87-89 and 93-95 have been amended. New claims 111-122 have been added. Claims 46-63, 66-72, 74-78, 80-83, 87-89, 92-95, 98 and 111-122 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments in the amendment. However, new grounds of rejection have been set forth. The present Office Action is NON-FINAL.

3. The disclosure is objected to because of the following informalities: p. 57, the primers need a sequence identifier; p. 64, there is no reference citation for Rosenow et al; p. 14, l. 5, what does "at position 2999" mean. Appropriate correction is required.

4. The use of trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

5. Claims 46-58, 60, 66-72, 74-78, 80-83, 87-89, 92-95, 112, and 116-122 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-58, 69-72, 74-78, 80-83, 87-89, 92-94 and 116-122 are vague and indefinite in the recitation of "an amino acid sequence"; does Applicant intend the entire amino acid sequence as set forth by the SEQ ID NO: or a portion of that amino acid sequence.

Claims 71 and 72 are vague and indefinite in the recitation of "capable". It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claims 51, 52, 60, 66 and 112 are vague and indefinite in the recitation of "up to 475 amino acids"; does Applicant intend this to mean that the polypeptide is 0 to 475 amino acids or 109 to 475 amino acids since claim 46 recites that the polypeptide comprises an amino acid sequence of SEQ ID NO: 5 which has 109 amino acids. However, claim 46 does recite "an amino acid sequence" which can

be less than the entire SEQ ID NO: 5; therefore it is not clear what Applicant intends.

Claim 52 is vague and indefinite in the recitation of “up to 460 amino acids”; does Applicant intend this to mean that the polypeptide is 0 to 460 amino acids or 109 to 460 amino acids since claim 46 recites that the polypeptide comprises an amino acid sequence of SEQ ID NO: 5 which has 109 amino acids. However, claim 46 does recite “an amino acid sequence” which can be less than the entire SEQ ID NO: 5; therefore it is not clear what Applicant intends.

Claim 57 is vague and indefinite in the recitation of “up to 475 amino acids”; does Applicant intend this to mean that the polypeptide is 0 to 475 amino acids or 106 to 475 amino acids since claim 54 recites that the polypeptide comprises an amino acid sequence of SEQ ID NO: 4 which has 106 amino acids. However, claim 54 does recite “an amino acid sequence” which can be less than the entire SEQ ID NO: 4; therefore it is not clear what Applicant intends.

Claim 58 is vague and indefinite in the recitation of “up to 460 amino acids”; does Applicant intend this to mean that the polypeptide is 0 to 460 amino acids or 106 to 460 amino acids since claim 54 recites that the polypeptide comprises an amino acid sequence of SEQ ID NO: 4 which has 106 amino acids. However, claim 54 does recite “an amino acid sequence” which can be less than the entire SEQ ID NO: 4; therefore it is not clear what Applicant intends.

Claims 74, 77, 80, 87-89, 92 and 118-120 are vague and indefinite in the recitation of “up to 328 amino acids”; does Applicant intend this to mean that the polypeptide is 0 to 328 amino acids or 107 to 328 amino acids since claim recites that the polypeptide comprises an amino acid sequence of SEQ ID NO: 11 which has 107 amino acids. However, the claim does recite “an amino acid sequence”

which can be less than the entire SEQ ID NO: 11; therefore it is not clear what Applicant intends. Further, claim 89 recites that the “polypeptide comprises the amino acid sequence set forth in SEQ ID NO: 7” and also depends from claim 87. Claim 87 indicates that the polypeptide has a maximum of 328 amino acids; however SEQ ID NO: 7, which is recited in claim 89, has 376 amino acids. It is not clear what the polypeptide of claim 89 encompasses.

Claims 75, 76, 78 and 95 are vague and indefinite in the recitation of “up to 376 amino acids”; does Applicant intend this to mean that the polypeptide is 0 to 376 amino acids or 254 to 475 amino acids since claim 75 recites that the polypeptide comprises an amino acid sequence of SEQ ID NO: 9 which has 254 amino acids. However, claim 75 does recite “an amino acid sequence” which can be less than the entire SEQ ID NO: 9; therefore it is not clear what Applicant intends.

Claims 81-83, 93, 94, 121 and 122 are vague and indefinite in the recitation of “up to 328 amino acids”; does Applicant intend this to mean that the polypeptide is 0 to 328 amino acids or 106 to 328 amino acids since claim 81 recites that the polypeptide comprises an amino acid sequence of SEQ ID NO: 10 which has 106 amino acids. However, the claim does recite “an amino acid sequence” which can be less than the entire SEQ ID NO: 10; therefore it is not clear what Applicant intends.

Claims 67, 68, 116 and 117 are vague and indefinite in the recitation of “up to 398 amino acids”; does Applicant intend this to mean that the polypeptide is 0 to 398 amino acids or 106 to 398 amino acids since claim 67 recites that the polypeptide comprises an amino acid sequence of SEQ ID NO: 4 which has 106 amino acids. However, the claim does recite “an amino acid sequence” which can

be less than the entire SEQ ID NO: 4; therefore it is not clear what Applicant intends.

The same rejection as above applies to claim 70, part c) for “up to 328 amino acids”; SEQ ID NO: 11 has 107 amino acids.

The same rejection as above applies to claim 70, part d) for “up to 376 amino acids”; SEQ ID NO: 9 has 254 amino acids.

The same rejection as above applies to claim 70, part e) for “up to 328 amino acids”; SEQ ID NO: 10 has 106 amino acids.

The same rejection as above applies to claim 69, part c) for “up to 328 amino acids”; SEQ ID NO: 11 has 107 amino acids.

The same rejection as above applies to claim 69, part d) for “up to 376 amino acids”; SEQ ID NO: 9 has 254 amino acids.

The same rejection as above applies to claim 69, part e) for “up to 328 amino acids”; SEQ ID NO: 10 has 106 amino acids.

The same rejection as above applies to claim 71, part a) for “up to 398 amino acids”; SEQ ID NO: 5 has 109 amino acids.

The same rejection as above applies to claim 71, part b) for “up to 398 amino acids”; SEQ ID NO: 4 has 106 amino acids.

The same rejection as above applies to claim 71, part c) for “up to 328 amino acids”; SEQ ID NO: 11 has 107 amino acids.

The same rejection as above applies to claim 71, part d) for “up to 376 amino acids”; SEQ ID NO: 9 has 254 amino acids.

The same rejection as above applies to claim 71, part e) for “up to 328 amino acids”; SEQ ID NO: 10 has 106 amino acids.

The same rejection as above applies to claim 72, part c) for “up to 328 amino acids”; SEQ ID NO: 11 has 107 amino acids.

The same rejection as above applies to claim 72, part d) for “up to 376 amino acids”; SEQ ID NO: 9 has 254 amino acids.

The same rejection as above applies to claim 72, part e) for “up to 328 amino acids”; SEQ ID NO: 10 has 106 amino acids.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 61, 71, part f), 98 and 113 are rejected under 35 U.S.C. 102(a) as being anticipated by Hammerschmidt et al (Mol. Microbiol., 1997, 25:1113-1124).

Hammerschmidt et al discloses isolated polypeptides from pneumococcal surface proteins and the claimed SEQ ID NO: 3 (see attached Sequence Search

printout). It is noted that claim 61 recites that the isolated polypeptide comprise the amino acid sequence set forth in SEQ ID NO: 3, wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, and said polypeptide does not bind choline and wherein said polypeptide is immunogenic.

With respect to claim 113, the reference is silent as to lectin activity. The reference is also silent regard to choline binding properties. However, the claimed invention is anticipated by the prior art of Hammerschmidt et al. The prior art anticipates the claimed invention by disclosing the claimed polypeptide isolated from the same source as Applicants'. The polypeptides in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polypeptide of Hammerschmidt et al, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polypeptides of the prior art are evidenced to meet the limitations of the claimed polypeptides, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polypeptides with the polypeptides of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polypeptides of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptides) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Determination of characteristics, which vary depending on the method of analysis, such as enzymatic activity, must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent.

9. Claims 54-58, 67-72, 116 and 117 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al (6573082).

Choi et al disclose isolated polypeptides from *Streptococcus pneumoniae* (abstract). Choi et al disclose SEQ ID NO: 38 which corresponds to Applicants' claimed SEQ ID NO: 4 and 22. Choi et al disclose that the polypeptide can be at least 70 % to 99% identical to the sequences as set forth in Table 1, which SEQ ID NO: 38 matches Applicants' SEQ ID NO: 4 and 22 (see also col. 3; col. 5; cols. 16-17). It is noted that the claims "wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, which the prior art discloses.

The reference is silent as to lectin activity. The reference is also silent regard to choline binding properties. However, the claimed invention is anticipated by the prior art of Choi et al. The prior art anticipates the claimed invention by disclosing the claimed polypeptide isolated from the same source as Applicants'. The polypeptides in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polypeptide of Choi et al, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polypeptides of the prior art are evidenced to meet the limitations of the claimed polypeptides, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polypeptides with the polypeptides of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polypeptides of the prior art does not

possess the same material structural and functional characteristics of the claimed polypeptides) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Determination of characteristics, which vary depending on the method of analysis, such as enzymatic activity, must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent.

10. Claims 71, part a), d), e), 88 and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Briles et al (6500613).

Briles disclose isolated polypeptides from *Streptococcus pneumoniae* (abstract). Briles et al disclose SEQ ID NO: 40 and 42 which corresponds to Applicants' claimed SEQ ID NO: 5, 9 and 10.

It is noted that the claims "wherein said amino acid sequence comprises at least one to 57 amino acid substitutions, which the prior art discloses. The reference is silent as to lectin activity. The reference is also silent regard to choline binding properties. However, the claimed invention is anticipated by the prior art of Briles et al. The prior art anticipates the claimed invention by disclosing the claimed polypeptide isolated from the same source as Applicants'. The polypeptides in the prior art are believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polypeptide of Briles et al, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polypeptides of the prior art are evidenced to meet the limitations of the claimed polypeptides, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polypeptides with the polypeptides of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polypeptides of the prior art does not possess the same material structural and functional characteristics of the claimed polypeptides) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Determination of characteristics, which vary depending on the method of analysis, such as enzymatic activity, must be made by the same method under the same or analogous conditions to show differences that are not otherwise clearly apparent.

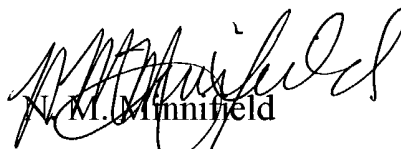
11. Claims 59, 62, 63, 111, 114 and 115 appear to be in condition for allowance.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

March 12, 2004